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The time period for reply, if any, is set in the attached communication.

1 RECORD OF ORAL HEARING
2 UNITED STATES PATENT AND TRADEMARK OFFICE
3
4 BEFORE THE BOARD OF PATENT APPEALS
5 AND INTERFERENCES
6

7
8 *Ex Parte* JUAN MANTELLE *et al.*
9

10 Appeal 2009-015395
11 Application 09/986,945
12 Technology Center 1600
13

14
15 Oral Hearing Held: Thursday, January 13, 2011
16

17
18 Before ERIC B. GRIMES, MELANIE L. MCCOLLUM and JEFFREY N.
19 FREDMAN, Administrative Patent Judges
20

21 ON BEHALF OF THE APPELLANT:
22 COURTENAY C. BRINCKERHOFF, ESQ.
23 3000 K Street, N.W., Sixth Floor
24 Washington, D.C. 20007-5109
25 (202) 295-4094
26

1 *The above-entitled matter came on for hearing on Thursday,*
2 *January 13, 2011, commencing at 1:17 p.m., at the U.S. Patent and*
3 *Trademark Office, 600 Dulany Street, 9th Floor, Alexandria, Virginia,*
4 *before Lori Beth Allen, Notary Public.*

5
6 THE CLERK: 015395, Ms. Brinckerhoff.

7 JUDGE GRIMES: Thank you.

8 MS. BRINCKERHOFF: From the docket numbers she read,
9 are we starting with Appeal 2009-15395?

10 JUDGE GRIMES: Yes.

11 MS. BRINCKERHOFF: Because we have two appeals.

12 JUDGE GRIMES: Yes. I see that. So we'll argue the first one,
13 and then we'll make sure that we know when we're moving to the second
14 one, since I don't think they're related.

15 MS. BRINCKERHOFF: No, they're not.

16 JUDGE GRIMES: Okay. If you wouldn't introducing your
17 colleague for the record, as well?

18 MS. BRINCKERHOFF: This is Jay Kolman from the
19 Applicant, Noven Pharmaceuticals.

20 MR. KOLMAN: Hi.

21 JUDGE GRIMES: Welcome.

22 MS. BRINCKERHOFF: I'm Courtenay Brinckerhoff.

23 The invention at issue in this case is directed to transdermal
24 drug delivery systems for formulating a low molecular weight drug that is
25 liquid at room temperature.

26 As discussed in the application, the invention addresses and
27 solves problems of formulating such liquid drugs in transdermal systems.

28 For example, the liquid drugs have the effect of plasticizing the
29 polymer platform that leads to legginess and gumminess and other physical
30 problems that make it unacceptable for use.

1 The invention arises from the discovery that if you formulate
2 those drugs in an acrylic polymer that has a high-shear resistance, the
3 resulting product has improved wear properties that avoids this problem.

4 There are six independent claims, but they all recite
5 compositions or methods where a low molecular weight drug with a
6 molecular weight of less than 300 Daltons -- and that's liquid at room
7 temperature -- is formulated in an acrylic-based polymer with a high-shear
8 resistance.

9 There are five rejections on appeal. There are two
10 indefiniteness rejections and three prior art rejections.

11 Does the Board have any particular questions on the
12 indefiniteness rejections, or want me to discuss those?

13 JUDGE GRIMES: Why don't you start with the prior art
14 rejections?

15 MS. BRINCKERHOFF: Okay.

16 JUDGE GRIMES: And if we have time, we can come back to
17 the ones --

18 MS. BRINCKERHOFF: There are two 102 rejections and there
19 is one 103 rejection. But the cited references do not teach or suggest
20 formulating a low-molecular weight drug.

21 JUDGE FREDMAN: Can we stop here, if we can focus on I
22 think the one that's perhaps the most to the point is the Miranda rejection.
23 That seems to me the one that I'd mostly have you discuss.

24 And the particular thing with Miranda that I'd like to focus on is
25 Miranda talks about essentially using -- using a transdermal delivery system
26 polymer blend.

27 And then at page 18, Miranda lists three different suitable
28 acrylic adhesives, including Duratec 80-1194, 80-1196, and 80-1197.

29 When you look at your specification, your specification at page
30 13 discusses suitable acrylic adhesives and specifically mentions the same
31 three Duratec numbers, 80-1194, 80-1196, and 80-1197.

1 I know in your argument you said that these have been
2 renamed, and for example, one of them, you say was renamed as 87-2194.

3 But your specification at page 23 specifically mentions Duratec
4 87-2194 and doesn't indicate that it's duplicative, nor did the three sheets that
5 you submitted as evidence prove themselves by saying, for example,
6 "87-2194 previously known as," or whatever.

7 So do you have any evidence that these three specific acrylic
8 adhesives, which your spec says are suitable, are in fact not suitable and
9 don't meet the requirement to the claim?

10 MS. BRINCKERHOFF: Let's see. That's a lot of questions
11 really there. But let me, I'll take it piece by piece.

12 The product sheets that we provided do correspond to these
13 polymers.

14 JUDGE FREDMAN: Do you have any evidence of that?

15 MS. BRINCKERHOFF: You know, we've made the assertion
16 under our obligation that --

17 JUDGE FREDMAN: Attorney argument -- evidence of a --

18 MS. BRINCKERHOFF: As attorney. We've submitted the
19 product sheets. We did put in a rule on 32 declaration that discusses sheer
20 resistance. I don't know if it addressed that issue, because the Examiner
21 never drilled down into this point.

22 The Examiner never questioned this evidence, so we never saw
23 a reason to sort of strengthen it, because the Examiner sort of seemed to just
24 bypass the whole issue.

25 With regard to the teachings in the specification, it's important
26 to understand that the specification was written to support several different
27 embodiments.

28 And the claims on appeal are directed to specific embodiments
29 for high-shear resistance polymers.

30 So when the specification talks about suitable acrylic adhesives,
31 it was doing so in a general context. Like, for example, Original Claim 1
32 didn't recite any high-shear resistant properties of the polymer.

1 Original Claim 1 was directed to any polymer, a system with
2 any polymer as long as it was substantially free of water.

3 And the specification --

4 JUDGE FREDMAN: No.

5 I don't know that the Examiner -- you said that he didn't drill
6 down to that. I think on page ten of the answer, he pretty much says that.
7 He points to Mantelle, which is really the same spec as you have, then says
8 that he points to these same polymers.

9 MS. BRINCKERHOFF: But I don't think he --

10 JUDGE FREDMAN: Or she --

11 MS. BRINCKERHOFF: I'm sorry, I don't think that she
12 questioned that our evidence didn't correlate to these polymers.

13 I think we just got the impression that she didn't understand the
14 point I'm making now that the specification teaches a much broader
15 disclosure of polymers than we're claiming;

16 And that's evident if you turn -- it's all the way at page 21 of the
17 specification, where it starts discussing the embodiment that we're claiming
18 now, which relates to the high-shear resistance polymers.

19 So the discussion on page 13, where these same polymers are
20 mentioned, relates to other embodiments. When you get to page 21, it talks
21 about the invention that we're claiming here. And then page 22 goes into the
22 shear resistance properties.

23 JUDGE GRIMES: Are there any particular -- oh, I see, on page
24 23, there are the adhesives that are appropriate for that embodiment? Is that
25 what you're saying?

26 MS. BRINCKERHOFF: Right. Which are not the same ones
27 that were discussed in Miranda.

28 JUDGE FREDMAN: Although, in fact, actually one of the
29 ones that is discussed, 87-2194, you submit the sheet for, and it doesn't
30 actually meet the requirements of the claim.

31 MS. BRINCKERHOFF: Well, again, we've also narrowed the
32 claims as to the scope of the shear resistance.

1 We never got the -- like the Examiner never raised the issue of
2 "Your evidence has this polymer number, but your specs have this polymer
3 number."

4 The Examiner was just making general statements, like, well,
5 they talk about using acrylate polymers. You talk about using acrylate
6 polymers.

7 So they must have the same properties.

8 So it never was apparent to us that the nature of the evidence
9 that we submitted was not sufficient.

10 JUDGE FREDMAN: Okay.

11 You can discuss the other reductions too. And I think they're
12 more straightforward.

13 MS. BRINCKERHOFF: So I guess another issue, another final
14 issue, with Miranda is it talks about, you know, it has many different
15 polymers and many different drugs, and no guidance to specifically choose a
16 low-molecular weight drive to formulate with a high-shear resistance
17 polymer.

18 Pfister is the other reference I cited in a 102 rejection. And
19 Pfister is directed to transdermal formulations with a silicone
20 pressure-sensitive adhesive, and a cohesive strengthening agent.

21 So to some extent, Pfister is addressing a problem that we're
22 addressing, but it solves it in a different approach by taking a silicone
23 platform and adding cohesive strengthening agents.

24 On the Examiner's side, Pfister, because it teaches that
25 carboxypolymethylene carbomers can be used as a cohesive strengthening
26 agent; but these are not high-shear resistance polymers.

27 The Examiner cited the shear data in Table C2 of Pfister, but as
28 we've explained, in prosecution and in our brief, that the data in that table is
29 not really on point.

30 First of all, the data relates to the composition as a whole, so the
31 whole platform of the silicone polymer with the cohesive strengthening

1 agent and other components, whereas our claims are reciting the specific
2 property of the acrylic-based polymer.

3 Also the data in Table C2 relates to examples where calcium
4 stearate was the strengthening agent, not where the carbomer was used.

5 So it's really irrelevant to the issue at hand.

6 As we also pointed out in our briefs, there was a number of
7 claims that would be separately patentable over Pfister.

8 Claims 1 and 22, and Dependent Claims 24 to 26 specify that
9 the acrylic-based polymer is a pressure-sensitive adhesive polymer, and the
10 carbomer that Pfister uses is not a pressure-sensitive adhesive.

11 And then Claims 19 and 21, and Dependent Claim 20, are
12 separately patentable because they recite that the pressure-sensitive adhesive
13 consists of the acrylic-based polymer; whereas Pfister uses a polymer as an
14 additive in his silicone system.

15 The obviousness rejection combines Pfister with Lee and
16 Horstman; but the secondary references don't bring you any closer to the
17 invention.

18 Lee was cited just for teaching an amount of drug that she cited
19 in Claim 6, and Horstman was cited for teaching the concept of formulating
20 amphetamine in a transdermal.

21 So we really think that the record shows that Miranda and
22 Pfister do not anticipate the claimed invention, and the combination of
23 Pfister, Lee, and Horstman did not render it obvious.

24 On the indefiniteness rejection, the Examiner was of the view
25 that this relates to the claims that exclude certain liquids from the
26 composition that are liquids having a boiling point below processing
27 temperatures.

28 JUDGE FREDMAN: The Examiner seemed to think that for
29 some reason, you wouldn't understand what below-processing temperatures
30 means.

1 MS. BRINCKERHOFF: Because there we didn't define it
2 right, or that you wouldn't know, without specifying the drug, you wouldn't
3 know what the drug's boiling point was.

4 JUDGE FREDMAN: Oh, unless, of course, we looked it
5 up -- yeah (laughing).

6 MS. BRINCKERHOFF: Right. Okay.

7 Are there any other questions that we could answer?

8 JUDGE GRIMES: Any other question?

9 JUDGE MCCOLLUM: No.

10 JUDGE GRIMES: No, I think that's all.

11 MS. BRINCKERHOFF: All right. I would just emphasize on
12 the evidence for Miranda that we do think that it does show that those
13 polymers are not within the scope of the Claim.

14 JUDGE GRIMES: All right. Thank you.

15 I think that's all for that case. We're off the record.

16 (Whereupon, at 1:31 p.m., the proceedings were concluded.)

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